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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,010	02/27/2006	Cynthia C. Bamdad	13150-70089US	8164
7590		08/22/2007		
JHK Law P O Box 1078 La Canada, CA 91012-1078			EXAMINER BRISTOL, LYNN ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,010	Applicant(s) BAMDAD, CYNTHIA C.	
	Examiner Lynn Bristol	Art-Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,13,14,17,27 and 57-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-6,13,14,17,27 and 57-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413).
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-6, 13, 14, 17, 27 and 57-62 are all the pending claims subject to lack of unity restriction.
2. Claims 7-12, 15, 16, 18-26, 28-56 and 63-195 were canceled in the amendment of 2/27/06.

Lack of Unity: Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to any antibody or antibody fragment thereof that binds to the MGFR region of the MUC1 protein, a method for producing an antibody against a peptide including a portion of a cell surface receptor associated with a ligand for promoting cell proliferation and a method of determining aggressiveness or metastatic potential of a cancer by contacting a sample with an antibody that binds to a peptide on a cell surface.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Antibodies recognizing a peptide epitope in the MGFR region of MUC1, methods of identifying the antibodies and methods of detecting cancer with the antibodies, were

Art Unit: 1643

already known before the priority date of the present application (8/26/03). For example, Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001) teach bivalent and monovalent antibodies that bind to MGFR of MUC1 and methods for producing antibodies [0099], and methods for diagnosing cancers [0139]. Because the claims broadly recite any antibody binding to any region within the MGFR domain of the MUC1 protein, and Bamdad et al. teach such antibodies, Applicants invention is not a contribution over the prior art, and therefore, the requirements for unity of invention are not met.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 13, 14 and 17, drawn to an antibody or antigen-binding fragment thereof binding to MGFR, a composition thereof and a kit thereof.

Group II, claim(s) 27, drawn to a method of producing an antibody or antigen-binding fragment thereof comprising providing any peptide including a portion of any cell surface receptor involved in the interaction with a ligand to produce cell proliferation.

Group III, claim(s) 57-62, drawn to a method of determining aggressiveness or metastatic potential of a cancer comprising contacting a sample with an antigen or antigen-binding fragment that binds to a peptide expressed on a cell surface.

Art Unit: 1643

5. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

6. The inventions of Group II and III are directed to methods that are independent and unrelated. The method of Group II does not require diagnosing a cancer much less the aggressiveness or metastatic potential of the cancer in a sample from a subject having or suspected of having the cancer whereas the method of Group III does not require a peptide including a portion of a cell surface receptor in order to generate a specific antibody against the peptide. Thus the inventions of Groups II and III are patentably distinct.

7. The inventions of Group I and II are related as a product and a process of making the product. The antibody of group I could be made by another materially different process such as synthetic chemical synthesis. Thus the inventions of Group I and II are patentably distinct.

8. The inventions of Group I and III are related as a product and a process of using the product. The method of diagnosing the aggressiveness or metastatic potential of a subject having or suspected of having a cancer could be practiced with a material different reagent such as a contrast dye and an diagnostic imaging system or MRI or CAT scan. Thus the inventions of Group I and III are patentably distinct.

Art Unit: 1643

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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